Docket No.: C1039.70077US00
(PATENT)

# IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

| | |
|---|---|
| Applicant: | Arthur M. Krieg |
| Serial No.: | 10/619279 |
| Confirmation No.: | 8248 |
| Filed: | July 14, 2003 |
| For: | IMMUNOSTIMULATORY NUCLEIC ACID MOLECULES |
| Examiner: | J.L. Epps Ford |
| Art Unit: | 1633 |

**Certificate of Mailing Under 37 CFR 1.8(a)**

I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being deposited with the U.S. Postal Service on the date shown below with sufficient postage as First Class Mail, in an envelope addressed to: MAIL STOP Issue Fee, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Dated: February 22, 2007

Sharon R. Lloyd

## TRANSMITTAL LETTER

**Mail Stop Issue Fee**
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Enclosed are the following items for filing in connection with the above-referenced Patent Application:

1. Application for Patent Term Adjustment Under 37 CFR § 1.705
2. Exhibits 1-5
3. Check in the amount of $200.00
4. Return Receipt Postcard.

The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith to our Deposit Account No. 23/2825, under Docket No. C1039.70077US00.

Dated: February 22, 2007

Respectfully submitted,

By _____
Helen C. Lockhart
Registration No.: 39,248
WOLF, GREENFIELD & SACKS, P.C.
Federal Reserve Plaza
600 Atlantic Avenue
Boston, Massachusetts 02210-2206
(617) 646-8000

1151233.1

DOCKET NO.: C1039.70077US00

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

| | |
|---|---|
| Applicant: | Krieg et al. |
| Serial No.: | 10/619,279 |
| Confirmation No.: | 8248 |
| Filed: | July 14, 2003 |
| For: | IMMUNOSTIMULATORY NUCLEIC ACID MOLECULES |
| Examiner: | Janet L. Epps Ford |
| Art Unit: | 1633 |

**CERTIFICATE OF MAILING UNDER 37 CFR §1.8(a)**

The undersigned hereby certifies that this document is being placed in the United States mail with first-class postage attached, addressed to MAIL STOP Issue Fee, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the 22nd day of February, 2007.

Sharon R. Lloyd

**Mail Stop Issue Fee**
Commissioner For Patents
P.O. Box 1450
Alexandria, VA 22313-1450

**APPLICATION FOR PATENT TERM ADJUSTMENT UNDER 37 CFR §1.705**

Sir:

Applicants file this Application for Patent Term Adjustment under 37 CFR §1.705(b) requesting reconsideration of the patent term adjustment (PTA) determination for serial number 10/619,279. Applicants provide herein a statement of the facts involved specifying the correct PTA and the basis under 37 CFR §1.702 for the PTA adjustment, relevant dates for which the adjustment is sought, and the adjustment to which the patent is entitled.

1. A Notice of Allowance and PTA calculation were mailed on January 24, 2007 from the US Patent and Trademark Office (USPTO) for US 10/619,279 (Copy enclosed herewith as Exhibit 1).

2. Applicants were accorded a PTA of 580 days for delays occurring at the USPTO.

3. The PTA was also reduced by 55 days based on an alleged delay in term by action of Applicants that took place in the period of May 9, 2006 through July 3, 2006.

4. A restriction requirement was mailed from the Office on April 5, 2006, setting a shortened statutory period for reply of one month (Copy enclosed herewith as Exhibit 2).

5. A reply to the restriction requirement was filed by Applicant on May 5, 2006 and received by the Office on May 9, 2006. (Copy enclosed herewith as Exhibit 3).

6. A preliminary amendment, modifying the claims consistent with the restriction requirement was filed by Applicant on June 29, 2006 and received by the Office on July 3, 2006 (referred to hereafter as the document filed in the USPTO on July 3, 2006, copy enclosed herewith as Exhibit 4).

7. The document filed in the USPTO on July 3, 2006 is listed on PAIR as a Supplemental Response.

8. Applicant submits that the document filed in the USPTO on July 3, 2006 was a preliminary amendment rather than a supplementary response.

9. According to 37 CFR §1.115 (a) a preliminary amendment is "an amendment that is received in the Office (§1.6) on or before the mail date of the first Office action under §1.104."

10. According to 37 CFR §1.104 an Examiner "shall make a thorough study thereof and shall make a thorough investigation of the prior art relating to the subject matter of the claimed invention. The examination shall be complete with respect to both compliance of the application or patent under reexamination with the applicable statutes and rules and to the patentability of the invention as claimed, as well as with respect to matters of form, unless otherwise indicated."

11. The restriction requirement did not provide a thorough examination of the claims including a thorough study of the prior art. Such an examination was conducted after Applicant elected claims for examination and was the subject matter of the Office action mailed on September 21, 2006 (Copy enclosed as Exhibit 5).

12. Applicant submitted a response to the restriction requirement. The response to restriction requirement was complete. The document filed in the USPTO on July 3, 2006 was not a supplemental response to the restriction requirement. Rather it was a preliminary amendment which voluntarily modified the scope of the claims, consistent with the species elected in the restriction requirement. The claims were not required to be amended by the restriction requirement.

13. Under 37 CFR §1.704(c), particular circumstances are delineated that are considered to constitute a failure of the Applicant to engage in reasonable efforts to conclude processing or

examination of an application and that result in a reduction of the period of PTA adjustment set forth in 37 CFR §1.703. The specific circumstances, which are set out in subsections of 37 CFR §1.704(c), include in part, paragraph 6, which reads:

> Submission of a preliminary amendment or other preliminary paper less than one month before the mailing of an Office action under 35 USC 132 or notice of allowance under 35 USC 151 that requires the mailing of a supplemental Office action or notice of allowance, in which case the period of adjustment set forth in §1.703 shall be reduced…

14. Applicant submits that the document filed in the USPTO on July 3, 2006 was a preliminary amendment, which was filed more than one month prior to a first substantive Office action and did not necessitate the filing of a supplemental Office action. The preliminary amendment was received by the Office more than one month prior to the issuance of a first Office Action. The first Office Action was mailed from the Office on September 21, 2006. The filing of the preliminary amendment did not necessitate the mailing of a supplemental office action. In fact, the first Office Action addressed the claims as they were amended in the preliminary amendment. The preliminary amendment, amended the scope of the claims, consistent with the restriction requirement. The amendments made in the preliminary amendment were consistent with Applicant's reasonable efforts to conclude processing and examination of the application.

15. The specific circumstances, which are set out in subsections of 37 CFR §1.704(c), also include in part, paragraph 8, which reads:

> Submission of a supplemental reply or other paper, other than a supplemental reply or other paper expressly requested by the examiner, after a reply has been filed, in which case the period of adjustment set forth in § 1.703 shall be reduced by the number of days, if any, beginning on the day after the date the initial reply was filed and ending on the date that the supplemental reply or other such paper was filed.

16. Under 37 CFR §1.704(a), when calculating the PTA adjustment, the period of adjustment of the term of a patent shall be reduced by a period equal to the period of time during which the applicant failed to engage in reasonable efforts to conclude prosecution.

17. Under 37 CFR §1.704(b), the Applicant is deemed to have failed to engage in reasonable efforts to conclude processing or examination of an application if a reply to any notice or action by the Office is not filed within three months. Specifically, 37 CFR §1.704(b) reads:

An applicant shall be deemed to have failed to engage in reasonable efforts to conclude processing or examination of an application of the cumulative total of any periods of time in excess of three months that are taken to reply to any notice or action by the Office making any rejection, objection, argument, or other request measuring such three month period from the date the notice was mailed or given to the applicant, in which case the period of adjustment set forth in §1.703 shall be reduced by the number of days, if any, beginning on the day after the date that is three months after the date of mailing or transmission of the Office communication notifying the applicant of the rejection, objection, argument, or other request and ending on the date the reply was filed. The period, or shortened statutory period, for reply that is set in the Office action or notice has no effect on the three-month period set forth in this paragraph.

18. Applicant submits that the reply causing the PTA reduction made by Applicant was both mailed and received by the Office within the three month period set forth in the above quoted paragraph. Although the Examiner had set a shortened statutory period for reply to a restriction requirement of one month, Applicant filed the reply to restriction requirement and preliminary amendment within three months of the mailing date of the restriction requirement. Thus, even if the preliminary amendment were considered to be a supplemental amendment, the document was filed within the three month period of time specified within the rules.

19. Under 37 CFR §1.704(b) Applicant's response to Office action if filed within three months of the mailing date of the Office action will not result in a reduction in PTA, regardless of whether an Examiner has set a shortened statutory period for reply.

20. In view of the fact that the document filed in the USPTO on July 3, 2006 was filed within three months of the restriction requirement, more than one month before the first office action, did not necessitate the mailing of a supplemental office action and was not a supplementary amendment, but rather a preliminary amendment, Applicant submits that the PTA should not be reduced by the 55 days from May 9, 2006 through July 3, 2006 time of the filing of the preliminary amendment and respectfully request PTA reconsideration.

21. A terminal disclaimer was not filed in the instant case and the patent is not subject to a terminal disclaimer.

22. There were no circumstances constituting a failure to engage in reasonable efforts to conclude processing or examination of such application as set forth in §1.704.

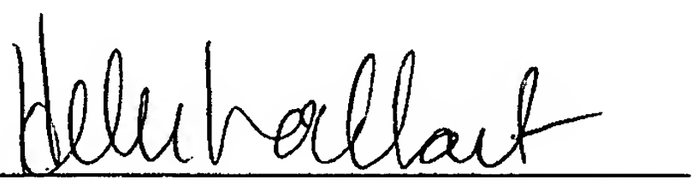
## Conclusion

Applicants provide above herein a statement of the facts involved specifying the correct PTA and the basis under 37 CFR §1.702 for the PTA adjustment, relevant dates for which the adjustment is sought, and the adjustment to which the patent is entitled. Applicants have also indicated that the patent is not subject to a terminal disclaimer.

In view of the fact that the preliminary amendment was filed within three months of the restriction requirement, more than one month before the first office action, did not necessitate the mailing of a supplemental office action and was not a supplementary amendment, Applicants submit that the 55 days from May 9, 2006 through July 3, 2006 time of the filing of the preliminary amendment, should not be charged against the PTA in this case and request reconsideration of the PTA and its adjustment from 525 days to 580 days.

Applicants submit herewith the fee of $200.00 for filing an application for patent term adjustment as set forth in 37 CFR §1.18(e). If there is an additional fee occasioned by this application and request that is not covered by an enclosed check, please charge any deficiency to Deposit Account No. 23/2825.

Respectfully submitted,

By: 

Helen C. Lockhart, Ph.D., Reg. No.: 39,248
Wolf, Greenfield & Sacks, P.C.
600 Atlantic Avenue
Boston, Massachusetts 02210-2206
Telephone: (617) 646-8000

Docket No.: C1039.70077US00
Date: February 22, 2007

EXHIBIT 1

UNITED STATES PATENT AND TRADEMARK OFFICE



UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/619,279 | 07/14/2003 | Arthur M. Krieg | C1039.70077US00 | 8248 |

7590 01/24/2007

Helen C. Lockhart
Wolf, Greenfield & Sacks, P.C.
Federal Reserve Plaza
600 Atlantic Avenue
Boston, MA 02210

| EXAMINER | |
|---|---|
| EPPS FORD, JANET L | |
| ART UNIT | PAPER NUMBER |
| 1633 | |

DATE MAILED: 01/24/2007

**Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)**
(application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 525 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 525 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

EXHIBIT 2

# UNITED STATES PATENT AND TRADEMARK OFFICE



UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/619,279 | 07/14/2003 | Arthur M. Krieg | C1039.70077US00 | 8248 |

7590 04/05/2006

Helen C. Lockhart
Wolf, Greenfield & Sacks, P.C.
Federal Reserve Plaza
600 Atlantic Avenue
Boston, MA 02210

| EXAMINER | |
|---|---|
| EPPS FORD, JANET L | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1633 | |

DATE MAILED: 04/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

| Application No. | Applicant(s) | |
|---|---|---|
| 10/619,279 | KRIEG, ARTHUR M. | |
| **Examiner** | **Art Unit** | |
| Anne Marie S. Wehbe | 1633 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

4)☒ Claim(s) 42-57 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 42-57 are subject to restriction and/or election requirement.

## Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

***Election/Restriction***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 46-47, drawn to a number of permutations and/or combinations of X1, X2, and X3, and X4 as required for the generic formula as set forth in the linking claim 42.

Applicant is required to elect a specific combination of permutations as required at minimum for the formula, wherein each of the X1-X4 must be identified for a specific nucleotide residue.

Each of the sequences with a specific combination of permutations are distinct in its structure and is expected to generate a sequence dependent immunostimulatory effect.

A search of one specific set of permutations for the formula in the prior art does not necessarily overlap with that of another. Further, due to the specificity in structural requirement for each of the specific set of permutation, a sequence search would also be distinct for its of the encompassed sequences and does not appear to be solely affected by any common structure as set forth in the formula, let alone the fact that the formula encompasses an enormous number of <100 nucleotide containing CpG unmethylated sequences. Therefore, a search of a

composition comprising anything more than a specific set of permutations is considered to be unduly burdensome to the examiner. For multiple inventions as set forth in claim 46, claim 42 is identified as the linking claims.

Note that the restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), as listed above. Upon the allowance of the linking claims, the restriction requirement as to the liked invention shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such (claim(s) depending from or including all the limitations of the allowable lining claim(s) is/are presented in a continuation or divisional application, the claims or the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler,* 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Should a specific set of permutations or combination of X1-X4 be elected, the

Elected set of combination/permutations is generic to a plurality of disclosed patentably distinct species comprising a specific sequence which is claimed specifically and listed in claim 52, and which is encompassed by the elected set of combination/permutations:

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species from as indicated above, even though this requirement is traversed. Each of the listed species is directed to a specific sequence of nucleotide residues, which may or may not be encompassed by the formula with the elected set of permutations. The claimed invention is drawn to an immunostimulatory composition which is desired to be used in an *in vivo* subject, and thus, has a distinct set of variables affecting consideration and examination of each of the distinct immunostimulatory species of sequence. Thereby, a search and examination of anything more than one of such together for patentablility would be unduly burdensome to the examiner.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner *Dave Nguyen* whose telephone number is **571-272-0731**.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center number, which is **571-273-8300.**

**ANNE M. WEHBE' PH.D**
**PRIMARY EXAMINER**

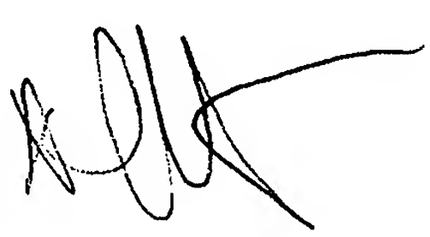


**EXHIBIT 3**



**Atty Docket No.:** C1039.70077US00 **WGS Date:** x05/05/06
**Inventor:** Arthur M. Krieg **Filing Date:** July 14, 2003
**Application No.:** 10/619279-Conf. #8248

**Title:** IMMUNOSTIMULATORY NUCLEIC ACID MOLECULES

**The USPTO Mail Room acknowledges receipt of the following on the date stamped hereon:**

Transmittal Form (1 page)

Response to Restriction Requirement (without Traverse) (2 pages)

Return Receipt Postcard



**Via:** First Class Mail - Certificate of Mailing Under 37 CFR 1.8(a)
**Sender's Initials:** HCL/jmw **Date Mailed:** May 5, 2006

1022497 1

Docket No.: C1039.70077US00
(PATENT)

# IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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| Applicant: | Arthur M. Krieg |
| Serial No.: | 10/619279 |
| Confirmation No.: | 8248 |
| Filed: | July 14, 2003 |
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| Examiner: | J.L. Epps Ford |
| Art Unit: | 1633 |

**Certificate of Mailing Under 37 CFR 1.8(a)**

I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being deposited with the U.S. Postal Service on the date shown below with sufficient postage as First Class Mail, in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Dated: May 5, 2006

Signature

## TRANSMITTAL LETTER

**Mail Stop Amendment**
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Enclosed are the following items for filing in connection with the above-referenced Patent Application:

1. Response to Restriction Requirement; and
2. Return Receipt Postcard.

The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith to our Deposit Account No. 23/2825, under Docket No. C1039.70077US00. A duplicate copy of this paper is enclosed.

Dated: May 5, 2006

Respectfully submitted,

By _____
Helen C. Lockhart
Registration No.: 39,248
WOLF, GREENFIELD & SACKS, P.C.
Federal Reserve Plaza
600 Atlantic Avenue
Boston, Massachusetts 02210-2206
(617) 646-8000

**WGS Date: x05/05/06**

1022498.1

Docket No.: C1039.70077US00
(PATENT)

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

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| Applicant: | Arthur M. Krieg |
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| Art Unit: | 1633 |

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Dated: May 5, 2006

Signature

## RESPONSE TO RESTRICTION REQUIREMENT

**Mail Stop Amendment**
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

In response to the restriction requirement set forth in the Office Action mailed April 5, 2006, Applicant hereby elects $X_1$ = G, $X_2$ = T, $X_3$ = T, and $X_4$ = T for continued examination.

## REMARKS

In response to the Restriction Requirement, Applicants have elected to prosecute $X_1$ = G, $X_2$ = T, $X_3$ = T, and $X_4$ = T.

Having made this election, Applicants expressly reserve the right to file one or more divisional applications on the subject matter of the nonelected claims.

## CONCLUSION

If this response is not considered timely filed and if the extension of time is otherwise absent or incorrect, Applicant hereby requests any necessary extension of time. If there is a fee occasioned by this response, including an extension fee, that is not covered by an enclosed check, please charge any deficiency to Deposit Account No. 23/2825.

Dated: May 5, 2006

Respectfully submitted,

By _____

Helen C. Lockhart
Registration No.: 39,248
WOLF, GREENFIELD & SACKS, P.C.
Federal Reserve Plaza
600 Atlantic Avenue
Boston, Massachusetts 02210-2206
(617) 646-8000

**WGS Date: x05/05/06**

**EXHIBIT 4**


Serial No. 10/619,279 Docket No. C1039-70077US00 Initials HCL
Title Immunostimulatory ~~Nucleic~~ Acid Molecules Conf No 8248
Applicant(s) Arthur M. Krieg Filing Date 7-14-03 WGS Date NDD

The USPTO Mail Room acknowledges receipt of the following on the date stamped hereon:

[ ] Mailing by Express Mail (37 CFR 1.10)
Express Mail Label No._____
[ ] Utility Patent Application
[ ] Non-Provisional [ ] Provisional
Tot Pages_____ Tot Claims_____
( pgs) Spec. ( pgs) Abstract ( pgs) Claims
[ ] Design Patent Application and Transmittal
[ ] Declaration(s) [ ] new [ ] copy from prior app
[ ] Drawings Sheets_____ Figures_____
[ ] Formal [ ] Informal
[ ] Utility Patent Application Transmittal
[ ] Fee Calculation Sheet (x2)
[✓] Application Data Sheet - Supplemental
[ ] Power of Attorney
[ ] Request for Approval and Entry of Drawings
[ ] Other_____

[ ] Provisional Application Cover Sheet
[ ] Inf. Dis. Statement (SB/08 or 1449)
[ ] Copies of Cited Refs. Encl.
[ ] US [ ] Foreign [ ] Other
[ ] RCE Transmittal
[ ] Copy of Notice to File Missing Parts
[✓] Amendment/~~Response~~ Preliminary
[ ] Petition for Ext. of Time (x2)
[ ] Issue Fee Transmittal
[ ] Assignment and Cover Sheet
[ ] Notice of Appeal
[ ] Brief
[✓] Transmittal Letter (x2)
[ ] Check for $_____ Check #_____
[✓] Cert. of Mailing under 37 C.F.R. 1.8


DATE MAILED June 29, 2006

PAT

DOCKET NO.: C1039.70077US00

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

| | |
|---|---|
| Applicant: | Arthur M. Krieg |
| Serial No.: | 10/619,279 |
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| Filed: | July 14, 2003 |
| For: | IMMUNOSTIMULATORY NUCLEIC ACID MOLECULES |
| Examiner: | J. L. Epps Ford |
| Art Unit: | 1633 |

**CERTIFICATE OF MAILING UNDER 37 C.F.R. §1.8(a)**

The undersigned hereby certifies that this document is being placed in the United States mail with first-class postage attached, addressed to MAIL STOP AMENDMENT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the 29 day of June, 2006.

Helen C. Lockhart, Ph.D., Reg. No. : 39,248

**MAIL STOP AMENDMENT**
Commissioner For Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Transmitted herewith are the following documents:

[X] Preliminary Amendment
[X] Supplemental Application Data Sheet
[X] Return Receipt Postcard

If the enclosed papers are considered incomplete, the Mail Room and/or the Application Branch is respectfully requested to contact the undersigned at (617) 646-8000, Boston, Massachusetts.

A check is not enclosed. If a fee is required, the Commissioner is hereby authorized to charge Deposit Account No. 23/2825. A duplicate of this sheet is enclosed.

Respectfully submitted,
*Arthur M. Krieg, Applicant*

By: _____

Helen C. Lockhart, Ph.D., Reg. No.: 39,248
Wolf, Greenfield & Sacks, P.C.
600 Atlantic Avenue
Boston, Massachusetts 02210-2206
Telephone: (617) 646-8000

Docket No.: C1039.70077US00
Date: June 29, 2006
**xNDDx**

.1047255.1

Docket No.: C1039.70077US00
(PATENT)

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

| | |
|---|---|
| Applicant: | Arthur M. Krieg |
| Serial No.: | 10/619279 |
| Confirmation No.: | 8248 |
| Filed: | July 14, 2003 |
| For: | IMMUNOSTIMULATORY NUCLEIC ACID MOLECULES |
| Examiner: | J. L. Epps Ford |
| Art Unit: | 1633 |

**Certificate of Mailing Under 37 CFR 1.8(a)**

I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being deposited with the U.S. Postal Service on the date shown below with sufficient postage as First Class Mail, in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Dated: June 29, 2006

Signature

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

**PRELIMINARY AMENDMENT**

Dear Sir:

**INTRODUCTORY COMMENTS**

Prior to examination on the merits, please amend the above-identified U.S. patent application as follows:

**Amendments to the Specification** begin on page 2 of this paper.

**Amendments to the Claims** begin on page 3 of this paper.

**Remarks/Arguments** begin on page 7 of this paper.

## AMENDMENTS TO THE SPECIFICATION

Please replace the paragraph immediately following the heading **Related Applications** on page 1, line 5, with the following paragraph:

This application is a continuation of co-pending U.S. Patent Application serial number 09/337,893 filed on June 21, 1999 and now pending which is a divisional of U.S. Serial No. 08/960,774, filed October 30, 1997, now issued as US 6,239,116 B1~~which is a continuation-in-part of U.S. Serial No. 08/738,652, filed October 30, 1996, now issued as US 6,207,646 B1, which is a continuation-in-part of U.S. Patent Application serial number 08/386,063, filed February 7, 1995 now issued as U.S. Patent No. 6,194,388, which is a continuation-in-part of U.S. Patent Application 08/276,358, filed July 15, 1994 which is now abandoned~~, each of which are incorporated herein by reference in their entirety.

## AMENDMENTS TO THE CLAIMS

A complete listing of claims is presented below with insertions indicated by underlining and deletions indicated by strikeouts and/or double bracketing. Please replace all prior versions, and listings, of claims in the application with the following list of claims:

1-41 (Canceled)

42. (Currently Amended) A ~~composition comprising~~ an immunostimulatory nucleic acid, having a sequence including at least the following formula:

~~5' TCNTX$_1$X$_2$CpGX$_3$X$_4$ 3'~~ 5' TCGTCGTTTTGTCGTTTTGTCGTT 3' (SEQ ID No. 46)

~~wherein X$_1$, X$_2$, X$_3$, and X$_4$ are nucleotides, N is a nucleic acid sequence composed of from about 0-25 nucleotides, wherein at least one nucleotide has a phosphate backbone modification, and~~ wherein the nucleic acid has less than or equal to 100 nucleotides, and wherein C is unmethylated.

43. (Currently Amended) The ~~composition~~ immunostimulatory nucleic acid of claim 42, wherein at least one nucleotide has a phosphate backbone modification and wherein the phosphate backbone modification is a phosphorothioate or phosphorodithioate modification.

44. (Currently Amended) The ~~composition~~ immunostimulatory nucleic acid of claim 42, wherein at least one nucleotide has a phosphate backbone modification and wherein the phosphate backbone modification occurs at the 5′ end of the nucleic acid.

45. (Currently Amended) The ~~composition~~ immunostimulatory nucleic acid of claim 42, wherein at least one nucleotide has a phosphate backbone modification and wherein the phosphate backbone modification occurs at the 3′ end of the nucleic acid.

46-50. (Canceled Herewith)

51. (Currently Amended) The ~~composition~~ immunostimulatory nucleic acid of claim 42, wherein the immunostimulatory nucleic acid is ~~8 to~~ less than 40 nucleotides in length.

52. (Canceled Herewith).

53. (Currently Amended) A method for stimulating an immune response, comprising administering to a subject the ~~composition~~ immunostimulatory nucleic acid of claim 42 in an effective amount to stimulate an immune response.

54. (Previously Presented) The method of claim 53, wherein the subject has or is at risk of developing asthma.

55. (Previously Presented) The method of claim 53, wherein the subject has or is at risk of developing allergy.

56. (Previously Presented) The method of claim 53, wherein the subject has or is at risk of developing cancer.

57. (Previously Presented) The method of claim 53, wherein the subject has or is at risk of developing infectious disease.

58. (New) The immunostimulatory nucleic acid of claim 42, wherein the immunostimulatory nucleic acid has a sequence consisting of TCGTCGTTTTGTCGTTTTGTCGTT (SEQ ID No. 46).

59. (New) The immunostimulatory nucleic acid of claim 58, wherein each internucleotide linkage has a phosphorothioate modification.

60. (New) The immunostimulatory nucleic acid of claim 58, further comprising an antigen.

61. (New) The immunostimulatory nucleic acid of claim 60, wherein the antigen is a vaccine and further comprising a conventional adjuvant.

62. (New) A method for treating cancer, comprising administering to a subject the immunostimulatory nucleic acid of claim 58 in an effective amount to treat cancer.

63. (New) A method for treating cancer, comprising administering to a subject the immunostimulatory nucleic acid of claim 59 in an effective amount to treat cancer.

64. (New) The method of claim 62, wherein the immunostimulatory nucleic acid is administered prior to along with or after administration of a chemotherapy.

65. (New) The method of claim 63, wherein the immunostimulatory nucleic acid is administered prior to along with or after administration of a chemotherapy.

66. (New) The method of claim 62, wherein the immunostimulatory nucleic acid is administered prior to along with or after administration of an immunotherapy.

67. (New) The method of claim 63, wherein the immunostimulatory nucleic acid is administered prior to along with or after administration of an immunotherapy.

68. (New) The method of claim 62, wherein the immunostimulatory nucleic acid is administered by injection.

69. (New) A method for generating an antibody in a mammal, comprising, administering to a mammal an effective amount of the immunostimulatory nucleic acid of claim 58 as an artificial adjuvant and an antigen to generate antibodies in the mammal.

70. (New) The method of claim 69, wherein the mammal is a human.

71. (New) The method of claim 69, further comprising isolating the antibody from the mammal.

72. (New) The method of claim 62, wherein the cancer is brain, lung, ovary, breast, prostate, or colon cancer

73. (New) The method of claim 62, wherein the cancer is a carcinomas or sarcoma.

74. (New) The immunostimulatory nucleic acid of claim 42, wherein the immunostimulatory nucleic acid is formulated as a composition with a pharmaceutically acceptable carrier.

## REMARKS

Applicant has amended claim 42 to recite a specific SEQ ID NO. (SEQ ID NO.: 46) that was pending in now canceled claim 52. As a result of the amendment to claim 42 claims 46-50 and 52 have been canceled and claims 43-45, 51 and 53 have been amended to be consistent with the new scope of claim 42. SEQ ID NO.: 46 falls within the scope of the invention elected for prosecution in response to the restriction requirement.

New dependent claims 58-74 have been added. Support for the limitations are found in pending claims or now canceled claims as well as throughout the specification. Support for claims 60 and 61 directed to an antigen (a vaccine is minimally comprised of an antigen) and conventional adjuvants is found on page 52 lines 14-20. Support for administration of a chemotherapy or immunotherapy is found on page 53 lines 5-8. Support for administration by injection is found on page 54 lines 10-11. Support for the different types of cancers is found on page 14 lines 2-4.

Support for a method of generating an antibody in a mammal by administering the composition as an artificial adjuvant is found in the specification in the summary of the invention, page 8 and on page 17 lines 10-11.

Applicant has also amended the related applications paragraph on the first page of the specification in view of the changes to the claims to reflect that the earliest effective priority date of the claims currently pending and directed to SEQ ID NO.: 46 is October 30, 1997. The claim of priority to US Patent Numbers 6,207,646 and 6,194,388 and US patent application number 08/276,358 has been dropped. An application data sheet reflecting this change has also been filed concurrently. No new matter has been added.

## Continuity Information

| | |
|---|---|
| This application is a: | Continuation |
| Claiming priority to: | |
| Serial Number: | 09/337,893 |
| Filing Date: | June 21, 1999 |
| Status: | Pending |

| | |
|---|---|
| Which is a: | Divisional |
| Claiming priority to: | |
| Serial Number: | 08/960,774 |
| Filing Date: | October 30, 1997 |
| Status: | Issued |

| | |
|---|---|
| ~~Which is a:~~ | ~~Continuation - in-part~~ |
| ~~Claiming priority to:~~ | |
| ~~Serial Number:~~ | ~~08/738,652~~ |
| ~~Filing Date:~~ | ~~October 30, 1996~~ |
| ~~Status:~~ | ~~Issued~~ |

| | |
|---|---|
| ~~Which is a:~~ | ~~Continuation - in-part~~ |
| ~~Claiming priority to:~~ | |
| ~~Serial Number:~~ | ~~08/386,063~~ |
| ~~Filing Date:~~ | ~~February 7, 1995~~ |
| ~~Status:~~ | ~~Issued~~ |

| | |
|---|---|
| ~~Which is a:~~ | ~~Continuation - in-part~~ |
| ~~Claiming priority to:~~ | |
| ~~Serial Number:~~ | ~~08/276,358~~ |
| ~~Filing Date:~~ | ~~July 15, 1994~~ |
| ~~Status:~~ | ~~Abandoned~~ |

## Assignee Information (when available)

| | |
|---|---|
| Name of Assignee: | University of Iowa Research Foundation |
| Address: | 214 Technology Innovation Center, Oakdale Research Campus<br>Iowa City, Iowa 52242 |

EXHIBIT 5

UNITED STATES PATENT AND TRADEMARK OFFICE



UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/619,279 | 07/14/2003 | Arthur M. Krieg | C1039.70077US00 | 8248 |

7590 09/21/2006

Helen C. Lockhart
Wolf, Greenfield & Sacks, P.C.
Federal Reserve Plaza
600 Atlantic Avenue
Boston, MA 02210

| EXAMINER | |
|---|---|
| EPPS FORD, JANET L | |
| ART UNIT | PAPER NUMBER |
| 1633 | |

DATE MAILED: 09/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Confirmation
Docketing

Initials

12/21/06"
HCL

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/619,279 | KRIEG, ARTHUR M. | |
| | Examiner | Art Unit | |
| | Janet L. Epps-Ford | 1633 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *03 July 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *42-74* is/are pending in the application.

4a) Of the above claim(s) *62-73* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *42-61 and 74* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892) ✓
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)✓ Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

### *Oath/Declaration*

1. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:
The specification to which the oath or declaration is directed has not been adequately identified. See MPEP § 602.

### *Election/Restrictions*

2. Applicant's election of immunostimulatory nucleic acid comprising wherein X1, X2, X3, and X4 are G, T, T, and T respectively as defined in formula: 5'-TCNTX1X2CpGX3X4-3' in the original claim 42, in the reply filed on 5-09-06 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

3. Claims 42-57 were the subject of the restriction requirement mailed, 4-05-06. In the reply filed 5-09-06, Applicants made the above election. In the amendment filed 7-03-06, Applicants added new claims 58-74. However, of the newly added claims, claims 58-61, and 74 are directed to the invention as originally presented. Newly added claims 62-73 appear to be directed to non-elected inventions for the reasons given below:

a. Claims 62-68, and 72-73 are drawn to a method for treating cancer comprising the administration of the immunostimulatory nucleic acid of SEQ ID NO: 46 in addition to chemotherapy or immunotherapy.

b. Claims 69-71 are drawn to a method for generating an antibody comprising the administration of an immunostimulatory nucleic acid in combination with an antigen.

The inventions of groups a-b are patentably distinct from the immunostimulatory nucleic acids, and methods for stimulating an immune response as set forth in original claims 42-57, and new claims 58-61 and 74. The methods of groups a-b set forth above are drawn to distinct methods comprising distinct objectives, distinct method steps, distinct reagents, and further comprising the production of distinct outcomes. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed comprise distinct objectives, distinct method steps, distinct reagents, and further comprising the production of distinct outcomes. Moreover, the newly added methods require different considerations under 35 USC 112, 1st paragraph. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

***Double Patenting***

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 42-61 and 74 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-49 of U.S. Patent No. 6,239,116 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are drawn to immunostimulatory nucleic acids having the nucleotide sequence as set forth in SEQ ID NO: 46, and to a generic methods for stimulating an immune response, however the issued claims which are drawn to a method for stimulating IL-6, and the method of stimulating natural killer cells represent a species of the broader method of the instant claims. The issued claims also disclose SEQ ID NO: 46 of the instant claims as one of the immunostimulatory nucleic acids used in the issued methods. Therefore, since the

methods of the issued claims represent a species of the broader instant claims, the issued claims are considered to anticipate the claims of the instant application.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps-Ford whose telephone number is 571-272-0757. The examiner can normally be reached on M-F, 10:00 AM through 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave T. Nguyen can be reached on 571-272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Janet L. Epps-Ford, Ph.D.
Primary Examiner
Art Unit 1633

*JLE*

| FORM PTO-1449/A and B (Modified) | APPLICATION NO.: 10/679,279 | ATTY. DOCKET NO.: C1039.70077US00 |
|---|---|---|
| **INFORMATION DISCLOSURE STATEMENT BY APPLICANT** | FILING DATE: July 14, 2003 | CONFIRMATION NO.: 8248 |
| | APPLICANT: Arthur M. Krieg, et al. | |
| Sheet 1 of 4 | GROUP ART UNIT: 1632 | EXAMINER: Not yet assigned |

**U.S. PATENT DOCUMENTS**

| Examiner Initial | Cite No. | U.S. Patent Document Number | U.S. Patent Document Kind Code | Name of Patentee or Applicant of Cited Document | Date of Publication or of issue of Cited Document MM-DD-YYYY |
|---|---|---|---|---|---|
| JE | * | 5,417,972 | | Bhat et al. | 05/23/1995 |
| | * | 5,445,938 | | Hanai et al. | 08/29/1995 |
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| | * | 5,679,647 | B1 | Carson et al. | 10/21/1997 |
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| | ** | 6,653,292 | B1 | Krieg et al. | 11/25/2003 |
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| | ** | US 2002/0098199 | A1 | Nest et al. | 07/25/2002 |
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| | ** | US 2002/0156033 | A1 | Raz et al. | 10/24/2002 |
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CANCELLED

JAN 09 2004

| FORM PTO-1449/A and B (Modified) | APPLICATION NO.: 10/619,279 | ATTY. DOCKET NO.: C1039.70077US00 |
|---|---|---|
| **INFORMATION DISCLOSURE STATEMENT BY APPLICANT** | FILING DATE: July 14, 2003 | CONFIRMATION NO.: 8248 |
| | APPLICANT: Arthur M. Krieg, et al. | |
| Sheet 2 of 4 | GROUP ART UNIT: 1632 | EXAMINER: Not yet assigned |

FEB 26 2007

**U.S. PATENT DOCUMENTS**

| Examiner's Initials | Cite No. | U.S. Patent Document Number | Kind Code | Name of Patentee or Applicant of Cited Document | Date of Publication or of issue of Cited Document MM-DD-YYYY |
|---|---|---|---|---|---|
| JE | ** | US 2003/0212028 | A1 | Raz et al. | 11-13-2003 |
| JE | ** | US 2003/0216340 | A1 | Van Nest et al. | 11-20-2003 |

**FOREIGN PATENT DOCUMENTS**

| Examiner's Initials | Cite No. | Foreign Patent Document Office/ Country | Number | Kind Code | Name of Patentee or Applicant of Cited Document (not necessary) | Date of Publication of Cited Document MM-DD-YYYY | Translation (Y/N) |
|---|---|---|---|---|---|---|---|
| JE | * | WO | 96/02560 | A1 | University of NC at Chapel Hill | 02/01/1996 | |
| JE | B1 | WO | 99/62923 | A2 | Dynavax Tech. Corp | 12/09/1999 | |
| JE | B2 | WO | 00/20039 | A1 | Regents of the University of CA | 04/13/2000 | |
| JE | B3 | WO | 00/62787 | A1 | Regents of the University of CA | 10/26/2000 | |

**OTHER ART — NON PATENT LITERATURE DOCUMENTS**

| Examiner's Initials | Cite No | Include name of the author (in CAPITAL LETTERS) title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, relevant page(s), volume-issue number(s), publisher, city and/or country where published. | Translation (Y/N) | |
|---|---|---|---|---|
| JE | * | AGGARWAL, S.K. et al., "Cell-Surface-Associated Nucleic Acid in Tumorigenic Cells Made Visible with Platinum-Complexes by Electron Microscopy", *Proc. Nat. Acad. Sci. USA*, March 1975, Pages 928-932, Vol. 72, No. 3 | | |
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| JE | * | COHEN, J., et al., "IL-12 Deaths: Explanation and a Puzzle"; *Science*, 10:270:5238:908 | | |
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| JE | * | GATELY, M., et al., "Interleukin-12: A Recently Discovered Cytokine with potential for Enhancing Cell-Mediated Immune Responses to Tumors", Cancer Investigation, 11:4:500-506, (1993) | | |
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| | APPLICANT: Arthur M. Krieg, et al. | |
| Sheet 3 of 4 | GROUP ART UNIT: 1632 | EXAMINER: Not yet assigned |

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| Examiner's Initials | No | Include name of the author (in CAPITAL LETTERS) title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, relevant page(s), volume-issue number(s), publisher, city and/or country where published. | Translation (Y/N) | |
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#EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

*a copy of this reference is not provided as it was previously cited by or submitted to the office in one of the prior applications, Serial No. 08/386,063 , filed February 7, 1995, Serial No. 08/738,652 ; filed October 30, 1996, Serial No. 09/337,619 , filed June 21, 1999 , and relied upon for an earlier filing date under 35 U.S.C. 120 (continuation, continuation-in-part, and divisional applications).

**copies of these patents and patent applications are not enclosed pursuant to the waiver by the USPTO of the requirement under 37 C.F.R. 1.98 (a)(2)(i) for patent applications filed after June 30, 2003.

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